

Conclusions: Facilitation using ROTA improves peri-procedural success without increasing complications for severely calcified ULM stenosis. Especially in no HD patients, excellent results were obtained at 1-year. However, the development of TLR-MB had still occurred in 38% of the HD patients despite optimal stent expansion.

TCT-410

Comparison of Coronary Artery Bypass Surgery, Percutaneous Drug-eluting Stent Implantation, and Medical Therapy for Unprotected Left Main Coronary Artery Disease

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Background: Unprotected left main coronary artery (ULMCA) disease is considered an indication for revascularization. However, in "real-world" clinical practice some patients receive medical therapy only. The aim of this study was to evaluate long-term results in patients with ULMCA disease in a "real-world" practice.

Methods: Between January 2006 and June 2011, 218 stable patients were diagnosed with de novo ULMCA stenosis. 52 (23.9%) patients received medical therapy only, coronary artery bypass grafting (CABG) was performed in 106 (48.6%) patients, percutaneous coronary intervention (PCI) in 60 (27.5%) patients. The composite of death, myocardial infarction, and stroke defined as major adverse cardiac and cerebrovascular events (MACCE) and target vessel revascularization (TVR) were defined as primary endpoints. The median follow-up period was 4 years.

Results: Baseline clinical and descriptive morphology of coronary artery disease revealed more comorbidities and more complex anatomies in the medical therapy group compare with CABG and PCI groups. Revascularization might not have been used due to physician's decision (operative risk considered excessive) in 24 (46.2%) cases or when patients refused revascularization in 28 (53.8%) cases. At 4-year follow-up MACCE rate was higher in nonsurgical group (34.6%) compare with CABG (13.2%; $p=0.002$) and PCI (14.5%; $p=0.016$) groups, but there was no difference between CABG and PCI groups. Survival in CABG (4.7%; $p<0.001$) and PCI (5.5%; $p=0.009$) groups was higher in compare with nonsurgical group (23.1%). On the multivariable Cox regression analysis, coronary revascularization (CABG and PCI) was independent predictor of long-term survival (HR 3.49; 95% CI 1.39-8.75; $P<0.001$).

Conclusions: PCI, like CABG improves survival for patients with unprotected left main coronary artery disease compared with medical therapy only in "real-world" clinical practice.

TCT-411

DES with bioresorbable polymer in the treatment of true bifurcation lesions – results of a large registry

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Background: Clinical outcomes after treatment of true bifurcation lesions (Medina classification: 1.1.1, 1.0.1 and 0.1.1) are in general inferior when compared to non-true bifurcation lesions (1.1.0, 0.0.1, 0.1.0). Therefore, our aim was to compare clinical outcomes of the patients with true and non-true bifurcation lesions treated with Nobori DES. This stent with open cell design and bioresorbable polymer is expected to perform well in lesions involving bifurcation.

Methods: Within the large, prospective, single-arm, multi-centre, eNOBORI registry, 898 patients (1541 lesions) had at least one bifurcation treated. Bifurcation lesions (BL) were divided into true (TBL, 512 patients; 927 lesions) and non-true bifurcation lesions (NTBL, 386 patients; 614 lesions). All adverse events are adjudicated by an independent clinical event committee. Primary endpoint of the study is target lesion failure (TLF) at 1 year.

Results: Patients in both groups had similar baseline characteristics, except that patients with TBL were less often male (74.8% vs 81.6%) and presented more often with renal failure (8.1% vs 4.7%). Average number of lesions treated per patient and stents implanted per lesion was higher in TBL than in NTBL (2.46 ± 1.50 vs 2.15 ± 1.50 ; $p<0.01$ and 1.28 ± 0.55 vs 1.16 ± 0.43 ; $p<0.01$, respectively). According to the Medina classification, the most frequent lesion type in TBL was [1.1.1] (66.2%), whereas in NTBL, [1.1.0] type was most abundant (42.9%). Direct stenting was more frequent in NTBL (35.9% vs 22.6%; $p<0.01$) and procedural success was similar in TBL and NTBL groups (98.2% vs 99.2%). In the TBL group, 3 patients died (1.0%; cardiac), 5 patients had TV-MI (1.7%) and 9 patients a TLR (3.0%) at 12 months, resulting in TLF of 6.0%. In the NTBL group, 1 patient died (0.5%; cardiac), 2 patients had TV-MI (0.9%) and 4 patients a TLR (1.9%), resulting in a TLF of 3.2%. No stent thrombosis were observed in the NTBL whereas 2 definite, subacute ST (0.48%) occurred in TBL patients ($p=NS$).

Conclusions: As expected, clinical outcomes after treatment of true bifurcation lesions were less favorable compared to the non-true bifurcation lesions however, the results of both cohorts are very good up to one year.

TCT-412

Long Term Outcome After Biodegradable Polymer Coating Biolimus-eluting Stent Implantation for Bifurcation Lesions

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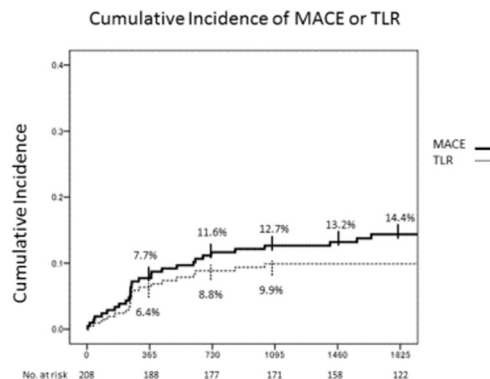
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Background: Long term clinical outcomes after biodegradable polymer eluting stents implantation at bifurcation lesions are unclear.

Methods: We analyzed 203 consecutive patients (208 bifurcation lesions treated) who were treated with PCI with biodegradable polymer coating biolimus-eluting stent (BES) exclusively at our institution between February 2005 and April 2009. They were followed up prospectively after the PCI (median follow-up 1931 days).

Results: One hundred sixty one patients (79%) were male and mean ages were 69 ± 10.3 . LMT lesions were 63(30%). Eighty lesions (38%) were treated by culotte stenting technique and other 128 lesions (61%) treated by stenting and kissing balloon technique (S-KBT). We evaluated the incidence for MACE, which were defined as a combined end point of cardiac death, MI or TLR. During that period, the rate of MACE, cardiac death, MI and TLR were 15.8%, 4.3%, 1.0%, 10.0% respectively. The rate of MACE and TLR were not different between culotte stenting technique and S-KBT ($p=0.35$ and $p=0.29$ respectively).

Conclusions: Long term outcome after PCI of bifurcation lesions with biodegradable polymer coating BES might be promising.



TCT-413

Complex versus simple stent strategy of bifurcation lesions of the left main coronary artery

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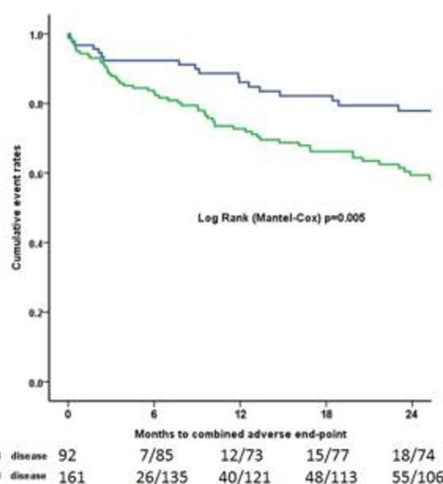
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Background: PCI to the left main coronary artery (LMCA) frequently involves the bifurcation with significant rates of repeat revascularisation. Single stent or 2 stent techniques may be related to the pattern of plaque distribution using the Medina system.

Methods: 254 patients underwent PCI to the distal LMCA, they were observed for a combined adverse endpoint (CAE), repeat revascularisation, MI and all-cause death. We categorised bifurcations into (Medina 1,1,1 and 0,1,1), both branch (BB) involvement or only a single branch (SB) involvement (all other Medina groups). Stent technique was categorised as simple (single stent) or complex (any 2 stent technique).

Results: 161 (63%) patients had BB involvement. Follow-up 2.26 (3.1) years. Median SYNTAX (IQR) 34.0 (17.0) and 25.0 (16.0), $p<0.000$. Median Additive EuroSCORE (IQR) was 7 (6) and 6 (5), $p<0.000$. Unadjusted CAE rates higher in the BB group at 30 days (5.6% vs 3.2%, $p=0.4$), 6 months (16.1% vs 7.5%, $p=0.05$), 12 months (24.8% vs 12.9%, $p=0.02$) and long term (43.5% vs 29.0%, $p=0.02$). A simple stent strategy was used in 59% of patients, 84% of the BB group. CAE rates were not different between patients treated by simple and complex techniques. After adjustment, BB disease and untreated severe right coronary artery (RCA) disease were independently associated with an increase in CAE, adjusted hazard ratios (95% CI) 1.84 (1.24 to 2.72) and 1.80 (1.22 to 2.65).



Conclusions: The presence of Medina classes 0,1,1 and 1,1,1, and the presence of significant RCA disease, but not stenting technique, are independent predictors of increased rates of CAE following LMCA PCI.

TCT-414

Dedicated 2-stent versus 1-stent Strategy in Diabetic Patients with Complex 'True' Bifurcation Lesion PCI using Everolimus-Eluting Stent

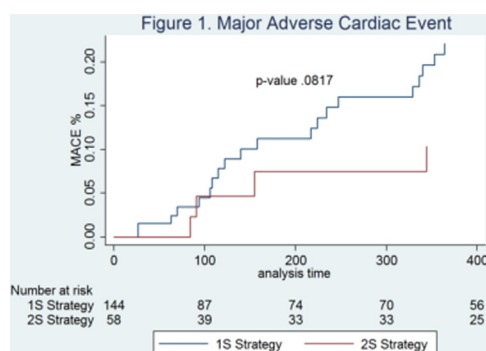
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Background: Percutaneous coronary intervention (PCI) of complex true coronary bifurcation lesions is challenging and whether to use a dedicated side branch stent is still debatable. To date there is no published study evaluating the safety and efficacy of using an Everolimus-eluting stent (EES) in diabetic patients with true bifurcation lesions treated with dedicated 2-stent (2S) vs. a provisional 1-stent (1S) technique. We sought to compare outcomes with a dedicated 2S vs. provisional 1S strategy among diabetic patients undergoing bifurcation stenting using EES.

Methods: We identified 202 diabetic patients with complex true bifurcation (Medina classification 1,1,1; 1,0,1; and 0,1,1) lesion who underwent bifurcation PCI using EES from February 2010 to December 2011. The PCI strategy was either a provisional 1S (n=144) or dedicated 2S (n=58) technique. Statistical analysis with all available follow-up data were constructed for time-to-event variables with Kaplan-Meier methodology and compared by log-rank test.

Results: The baseline characteristics were well matched between two PCI strategies. In-hospital major adverse cardiac event (MACE) and postprocedure MI (CK-MB >3x Normal, 8.33% vs. 10.34%, P=0.65). At 1-year follow-up, MACE tended to be lower for the 2S compared to the provisional 1S approach with the time to event analysis depicted in Figure 1 (P=0.08).



Conclusions: The conservative provisional 1S technique tended to have greater MACE events compared to the dedicated 2S technique in diabetic patients after treatment of complex true bifurcation lesions using newer generation EES.

TCT-415

Optimized Final Kissing Balloon Post-dilation For Provisional Bifurcation Stenting

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Background: Main vessel stenting with final kissing balloon dilatation (FKBD) is widely employed, but many technical variations are possible that may affect the final result. In this study, two different FKBD strategies were investigated.

Methods: Finite element simulations were used to virtually deploy and post-dilate three stent platforms within three bifurcation models, mimicking a range of coronary bifurcation anatomies. Stents were sized according to the distal branch diameter and deployed to a diameter of 3.2mm following the compliance charts. During a second step, a shorter (but larger) balloon was used to post-dilate the proximal stent segment. Two FKBD strategies were evaluated: "simultaneous FKBD" (n=27) and "modified FKBD" (n=27). In the simultaneous FKBD, both the side and main branch balloon were simultaneously inflated and deflated, with a maximal balloon pressure of 12atm. In the modified FKBD, the side branch balloon was inflated to a pressure of 12atm, and then deflated to 4atm. Subsequently, the main branch balloon was inflated to a pressure of 12atm. Eventually, both balloons were fully deflated. The following quantitative measures were used to compare both FKBD strategies: percentage of side branch obstruction, ellipticity index (the ratio of the maximal to the minimal diameter in the proximal stent segment) and percentage of malapposed struts (defined as strut-artery distance of more than 100 micron). The accuracy of the computer simulation results was evaluated by comparing the virtually predicted stent deformations with stent deformations observed during microCT visualised in-vitro bench testing.

Results: Modified FKBD results in a lower ostial stenosis as compared to simultaneous FKBD (15±9% vs. 20±11%, p<0.001) and also reduces the elliptical stent deformation (ellipticity index = 1.17±0.05 vs. 1.36±0.06, p<0.001). The amount of malapposed stent struts was not influenced by the FKBD technique (modified FKBD: 6.3±3.6%, simultaneous FKBD: 6.4±3.4%, p=0.212).

Conclusions: The modified FKBD procedure reduces the elliptical stent deformation and optimises the side branch access while avoiding stent distortion within the main vessel.

TCT-416

Impact of Diabetes Status on Long-Term (6 years) Outcomes after Percutaneous Coronary Intervention of Left Main Disease: Result from a Real World Experience of 1,528 Consecutive Patients

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Background: Scant data exist regarding the impact of diabetes mellitus (DM) status on percutaneous coronary intervention (PCI) for left main (LM) coronary artery disease. We sought to compare the impact of the presence of DM at baseline among pts undergoing LM PCI on long-term ischemic outcomes.

Methods: Data from all consecutive patients from a single center were prospectively collected. Pts were stratified according to the presence or absence of DM at baseline. Coronary angiograms were analyzed by an independent angiographic core laboratory and all events adjudicated by an independent clinical events committee. Adverse ischemic outcomes were compared between the 2 groups up to 6-year follow-up.

Results: Between Jan 2004 and Dec 2010, 1,528 consecutive pts underwent LM PCI. DM was present in 369 (24.1%) pts. Pts with DM were more likely to have increased weight, prior MI, hypertension, dyslipidemia and prior stroke. Angiographically, DM pts presented more frequently with 3-vessel-disease, 1,1,1 medina bifurcation and higher baseline SYNTAX score. Despite having more lesions treated and more stents implanted, DM pts had higher residual SYNTAX score after revascularization. One-year dual antiplatelet therapy compliance rates were high among the complete cohort (95.3%) and similar between both groups. At 6-year follow-up, no differences were seen in rates of all-cause death (6.0% vs. 4.7%, p=0.36) and definite/probable stent thrombosis (ST; 1.6% vs. 1.7%, p=0.90) between groups. However, DM pts had a higher rate of target lesion revascularization (TLR; 8.4% vs. 4.4%, p=0.005), target vessel revascularization (TVR; 13.6% vs. 8.1%, p=0.003), and stroke (4.9% vs. 1.3%; p=0.002). By multivariate analysis,